

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiff,

V.

MYLAN INC., MYLAN
PHARMACEUTICALS INC. and MYLAN
LABORATORIES LIMITED,

Defendants.

Civil Action No.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. (“Otsuka”), by way of Complaint against Defendants Mylan Inc., Mylan Pharmaceuticals Inc. (“Mylan Pharmaceuticals”) and Mylan Laboratories Limited (“Mylan Labs. Ltd.”) (collectively, “Mylan”), alleges as follows:

THE PARTIES

1. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan. Otsuka is engaged in the research, development, manufacture and sale of pharmaceutical products.

2. Upon information and belief, Mylan Inc. is a corporation organized and existing under the laws of Pennsylvania, having its principal place of business at 1000 Mylan Blvd., Canonsburg, PA 15317.

3. Upon information and belief, Mylan Pharmaceuticals is a corporation organized and existing under the laws of West Virginia, having its principal place of business at 781

Chestnut Ridge Road, Morgantown, WV 26505. Upon information or belief, Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Inc.

4. Upon information and belief, Mylan Labs. Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills, Hyderabad 500034, India. Upon information, Mylan Labs. Ltd. is a subsidiary of Mylan Inc. Upon information and belief, Mylan Inc.'s 2011 10-K Report states that Mylan Inc. "holds approximately 98% ownership and control in Mylan Laboratories Limited."

NATURE OF THE ACTION

5. This is an action for infringement of U.S. Patent No. 8,017,615 ("the '615 patent"), U.S. Patent No. 8,580,796 ("the '796 patent"), U.S. Patent No. 8,642,760 ("the '760 patent"), U.S. Patent No. 7,053,092 ("the '092 patent") and U.S. Patent No. 8,642,600 ("the '600 patent") arising under the United States patent laws, Title 35, United States Code, § 100 *et seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Mylan Pharmaceuticals' filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to manufacture, use, sale, offer to sell and import generic pharmaceutical products ("Mylan Pharmaceuticals' generic products") prior to the expiration of the asserted patents.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has jurisdiction over Mylan Inc. Upon information and belief, Mylan Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug

products, including generic drug products. Upon information and belief, Mylan Inc., directly or through its subsidiaries, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. According to Mylan Inc.'s 10-K Report, filed February 27, 2014, Mylan "is a leading global pharmaceutical company which develops, licenses, manufactures, markets and distributes generic, branded generic and specialty pharmaceuticals," "had 324 ANDAs pending FDA approval" as of December 31, 2013, and "holds the number one ranking in the U.S. generics prescription market in terms of sales and the number two ranking in terms of prescriptions dispensed." Upon information and belief, Mylan's website states that "[o]ne out of every 11 U.S. prescriptions dispensed, brand name or generic, is filled with a Mylan product." See <http://www.mylan.com/businesses/generic-products>. Upon information and belief, Mylan Inc. owns a subsidiary, Mylan Specialty, located at 110 Allen Rd., Basking Ridge, NJ 07920. Upon information and belief, Mylan Inc. is registered (No. 5003762) as a Manufacturer and Wholesaler in the State of New Jersey. Upon information and belief, Mylan Inc. is registered (Entity ID 0100971292) with the State of New Jersey Division of Revenue and Enterprise Services. Mylan Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

8. This Court has jurisdiction over Mylan Pharmaceuticals. Upon information and belief, Mylan Pharmaceuticals is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Mylan Pharmaceuticals, directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Mylan Pharmaceuticals purposefully has conducted and continues to conduct business,

directly or indirectly, in this judicial district, and this judicial district is the likely destination of Mylan Pharmaceuticals' generic products. According to Mylan Inc.'s 10-K Report, dated February 27, 2013, Mylan Pharmaceuticals is Mylan's "primary U.S. pharmaceutical research, development, manufacturing, marketing and distribution subsidiary[.]" Upon information and belief, Mylan Pharmaceuticals is registered (Entity ID 0100214277) with the State of New Jersey Division of Revenue and Enterprise Services. Mylan Pharmaceuticals has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

9. This Court has jurisdiction over Mylan Labs. Ltd. Upon information and belief, Mylan Labs. Ltd., directly or indirectly, is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Mylan Labs. Ltd., directly or indirectly, manufactures, markets and sells generic drug products throughout the United States and this judicial district. Upon information and belief, Mylan Labs. Ltd. is a subsidiary of Mylan Inc. and shares common corporate directors with Mylan Inc. Upon information and belief, Mylan Labs. Ltd. "is one of the world's largest manufacturers and suppliers of active pharmaceutical ingredients (APIs)." *See* http://mylanlabs.in/about_us.aspx. Upon information and belief, Mylan Inc.'s 10-K Report, filed February 27, 2014, states that "[t]hrough Mylan Laboratories Limited, an Indian subsidiary, we manufacture and supply low cost, high quality API for our own products and pipeline" Upon information and belief, Mylan Labs. Ltd. is the DMF holder for Mylan's aripiprazole API. *See* http://mylanlabs.in/our_businesses/~media/mylan-india/pdf/ANNEX%204_Therapeutic%20Segments%20-%20API.ashx. Upon information and belief, Mylan Labs. Ltd.'s wholly-owned subsidiary, Mylan Laboratories, Inc., has its principal place of business at 76 S Orange Avenue,

South Orange, NJ 07079. Upon information and belief, Mylan Laboratories, Inc. is registered (No. 5003419) as a Drug Wholesaler in the State of New Jersey. Mylan Labs. Ltd. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

10. Upon information and belief, Mylan Inc., Mylan Pharmaceuticals and Mylan Labs. Ltd, operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States including in this judicial district. Upon information and belief, Mylan Inc. describes Mylan Inc. and its subsidiaries as a company “with true vertical integration.” *See* <http://www.mylan.com/company/about-us>.

11. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

FIRST COUNT FOR PATENT INFRINGEMENT

12. The U.S. Patent and Trademark Office (“PTO”) issued the ’615 patent on September 13, 2011, entitled “Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof.” A copy of the ’615 patent is attached as Exhibit A.

13. Otsuka is the owner of the ’615 patent by virtue of assignment.

14. The ’615 patent expires on December 16, 2024 (including pediatric exclusivity).

15. The ’615 patent is directed to and claims, *inter alia*, pharmaceutical solid oral preparations, as well as processes for preparing pharmaceutical solid oral preparations.

16. Otsuka is the holder of New Drug Application (“NDA”) No. 21-436 for aripiprazole tablets, which the FDA approved on November 15, 2002.

17. Otsuka lists the '615 patent in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-436.

18. Otsuka markets aripiprazole tablets in the United States under the trademark Abilify®.

19. Upon information and belief, Mylan Pharmaceuticals submitted ANDA No. 206-240 to the FDA, under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking approval to manufacture, use, import, offer to sell and sell Mylan Pharmaceuticals' generic products in the United States.

20. Otsuka received a letter from Mylan Pharmaceuticals dated May 28, 2014, purporting to include a Notice of Certification for ANDA No. 206-240 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 ("Mylan Pharmaceuticals' 206-240 letter") as to the '615 patent.

21. Mylan Pharmaceuticals' 206-240 letter alleges that the name of the drug product that is subject of the Mylan ANDA is aripiprazole oral tablets.

22. Upon information and belief, Mylan Pharmaceuticals' generic products will, if approved and marketed, infringe at least one claim of the '615 patent.

23. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals has infringed at least one claim of the '615 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206-240 seeking approval to manufacture, use, import, offer to sell and sell Mylan Pharmaceuticals' generic products before the expiration date of the '615 patent.

24. Upon information and belief, Mylan Pharmaceuticals' actions relating to ANDA No. 206-240 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Mylan Inc., Mylan Pharmaceuticals and Mylan Labs. Ltd.

SECOND COUNT FOR PATENT INFRINGEMENT

25. Otsuka realleges, and incorporates in full herein, paragraphs 16, 18, 19 and 21.

26. The PTO issued the '796 patent on November 12, 2013, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '796 patent is attached as Exhibit B.

27. Otsuka is the owner of the '796 patent by virtue of assignment.

28. The '796 patent expires on March 25, 2023 (including pediatric exclusivity).

29. The '796 patent is directed to and claims, *inter alia*, aripiprazole crystals.

30. Otsuka lists the '796 patent in the Orange Book for NDA No. 21-436.

31. Mylan Pharmaceuticals' 206-240 letter purports to include a Notice of Certification for ANDA No. 206-240 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '796 patent.

32. Upon information and belief, Mylan Pharmaceuticals' generic products will, if approved and marketed, infringe at least one claim of the '796 patent.

33. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals has infringed at least one claim of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206-240 seeking approval to manufacture, use, import, offer to sell and sell Mylan Pharmaceuticals' generic products before the expiration date of the '796 patent.

34. Upon information and belief, Mylan Pharmaceuticals' actions relating to ANDA No. 206-240 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Mylan Inc., Mylan Pharmaceuticals and Mylan Labs. Ltd.

THIRD COUNT FOR PATENT INFRINGEMENT

35. Otsuka realleges, and incorporates in full herein, paragraphs 16, 18, 19 and 21.

36. The PTO issued the '760 patent on February 4, 2014, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '760 patent is attached as Exhibit C.

37. Otsuka is the owner of the '760 patent by virtue of assignment.

38. The '760 patent expires on March 25, 2023 (including pediatric exclusivity).

39. The '760 patent is directed to and claims, *inter alia*, aripiprazole drug substance.

40. Otsuka lists the '760 patent in the Orange Book for NDA No. 21-436.

41. Mylan Pharmaceuticals' 206-240 letter purports to include a Notice of Certification for ANDA No. 206-240 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '760 patent.

42. Upon information and belief, Mylan Pharmaceuticals' generic products will, if approved and marketed, infringe at least one claim of the '760 patent.

43. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals has infringed at least one claim of the '760 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206-240 seeking approval to manufacture, use, import, offer to sell and sell Mylan Pharmaceuticals' generic products before the expiration date of the '760 patent.

44. Upon information and belief, Mylan Pharmaceuticals' actions relating to ANDA No. 206-240 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Mylan Inc., Mylan Pharmaceuticals and Mylan Labs. Ltd.

FOURTH COUNT FOR PATENT INFRINGEMENT

45. Otsuka realleges, and incorporates in full herein, paragraphs 16, 18, 19 and 21.

46. The PTO issued the '092 patent on May 30, 2006, entitled "5-HT1A Receptor Subtype Agonist." A copy of the '092 patent is attached as Exhibit D.

47. Otsuka is the owner of the '092 patent by virtue of assignment.

48. The '092 patent expires on January 28, 2022.

49. The '092 patent is directed to and claims, *inter alia*, methods of treatment comprising administering aripiprazole.

50. Otsuka lists the '092 patent in the Orange Book for NDA No. 21-436.

51. Mylan Pharmaceuticals' 206-240 letter purports to include a Notice of Certification for ANDA No. 206-240 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '092 patent.

52. Upon information and belief, Mylan Pharmaceuticals' generic products will, if approved and marketed, infringe at least one claim of the '092 patent.

53. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals has infringed at least one claim of the '092 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206-240 seeking approval to manufacture, use, import, offer to sell and sell Mylan Pharmaceuticals' generic products before the expiration date of the '092 patent.

54. Upon information and belief, Mylan Pharmaceuticals' actions relating to ANDA No. 206-240 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Mylan Inc., Mylan Pharmaceuticals and Mylan Labs. Ltd.

FIFTH COUNT FOR PATENT INFRINGEMENT

55. Otsuka realleges, and incorporates in full herein, paragraphs 16, 18, 19 and 21.

56. The PTO issued the '600 patent on February 4, 2014, entitled "Method of Treating Autism." A copy of the '600 patent is attached as Exhibit E.

57. Otsuka is the owner of the '600 patent by virtue of assignment.

58. The '600 patent expires on July 28, 2022 (including pediatric exclusivity).

59. The '600 patent is directed to and claims, *inter alia*, methods of treatment comprising administering aripiprazole.

60. Otsuka lists the '600 patent in the Orange Book for NDA No. 21-436.

61. Mylan Pharmaceuticals' 206-240 letter purports to include a Notice of Certification for ANDA No. 206-240 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '600 patent.

62. Upon information and belief, Mylan Pharmaceuticals' generic products will, if approved and marketed, infringe at least one claim of the '600 patent.

63. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals has infringed at least one claim of the '600 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206-240 seeking approval to manufacture, use, import, offer to sell and sell Mylan Pharmaceuticals' generic products before the expiration date of the '600 patent.

64. Upon information and belief, Mylan Pharmaceuticals' actions relating to ANDA No. 206-240 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Mylan Inc., Mylan Pharmaceuticals and Mylan Labs. Ltd.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendants Mylan Inc., Mylan Pharmaceuticals and Mylan Labs. Ltd. on the patent infringement claims set forth above and respectfully requests that this Court:

- 1) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Mylan has infringed at least one claim of the '615 patent through Mylan Pharmaceuticals' submission of ANDA No. 206-240 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Mylan Pharmaceuticals' generic products in the United States before the expiration of the '615 patent;
- 2) order that the effective date of any approval by the FDA of Mylan Pharmaceuticals' generic products be a date that is not earlier than the expiration of the '615 patent, or such later date as the Court may determine;
- 3) enjoin Mylan from the manufacture, use, import, offer for sale and sale of Mylan Pharmaceuticals' generic products until the expiration of the '615 patent, or such later date as the Court may determine;
- 4) enjoin Mylan and all persons acting in concert with Mylan, from seeking, obtaining or maintaining approval of Mylan Pharmaceuticals' ANDA No. 206-240 until expiration of the '615 patent;
- 5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Mylan has infringed at least one claim of the '796 patent through Mylan Pharmaceuticals' submission of ANDA No. 206-240 to the FDA to obtain approval to manufacture, use, import, offer to sell

and sell Mylan Pharmaceuticals' generic products in the United States before the expiration of the '796 patent;

- 6) order that the effective date of any approval by the FDA of Mylan Pharmaceuticals' generic products be a date that is not earlier than the expiration of the '796 patent, or such later date as the Court may determine;
- 7) enjoin Mylan from the manufacture, use, import, offer for sale and sale of Mylan Pharmaceuticals' generic products until the expiration of the '796 patent, or such later date as the Court may determine;
- 8) enjoin Mylan and all persons acting in concert with Mylan, from seeking, obtaining or maintaining approval of Mylan Pharmaceuticals' ANDA No. 206-240 until expiration of the '796 patent;
- 9) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Mylan has infringed at least one claim of the '760 patent through Mylan Pharmaceuticals' submission of ANDA No. 206-240 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Mylan Pharmaceuticals' generic products in the United States before the expiration of the '760 patent;
- 10) order that the effective date of any approval by the FDA of Mylan Pharmaceuticals' generic products be a date that is not earlier than the expiration of the '760 patent, or such later date as the Court may determine;
- 11) enjoin Mylan from the manufacture, use, import, offer for sale and sale of Mylan Pharmaceuticals' generic products until the expiration of the '760 patent, or such later date as the Court may determine;

- 12) enjoin Mylan and all persons acting in concert with Mylan, from seeking, obtaining or maintaining approval of Mylan Pharmaceuticals' ANDA No. 206-240 until expiration of the '760 patent;
- 13) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Mylan has infringed at least one claim of the '092 patent through Mylan Pharmaceuticals' submission of ANDA No. 206-240 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Mylan Pharmaceuticals' generic products in the United States before the expiration of the '092 patent;
- 14) order that the effective date of any approval by the FDA of Mylan Pharmaceuticals' generic products be a date that is not earlier than the expiration of the '092 patent, or such later date as the Court may determine;
- 15) enjoin Mylan from the manufacture, use, import, offer for sale and sale of Mylan Pharmaceuticals' generic products until the expiration of the '092 patent, or such later date as the Court may determine;
- 16) enjoin Mylan and all persons acting in concert with Mylan, from seeking, obtaining or maintaining approval of Mylan Pharmaceuticals' ANDA No. 206-240 until expiration of the '092 patent;
- 17) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Mylan has infringed at least one claim of the '600 patent through Mylan Pharmaceuticals' submission of ANDA No. 206-240 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Mylan Pharmaceuticals' generic products in the United States before the expiration of the '600 patent;

- 18) order that the effective date of any approval by the FDA of Mylan Pharmaceuticals' generic products be a date that is not earlier than the expiration of the '600 patent, or such later date as the Court may determine;
- 19) enjoin Mylan from the manufacture, use, import, offer for sale and sale of Mylan Pharmaceuticals' generic products until the expiration of the '600 patent, or such later date as the Court may determine;
- 20) enjoin Mylan and all persons acting in concert with Mylan, from seeking, obtaining or maintaining approval of Mylan Pharmaceuticals' ANDA No. 206-240 until expiration of the '600 patent;
- 21) declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Otsuka costs, expenses and disbursements in this action, including reasonable attorney fees; and
- 22) award Otsuka such further and additional relief as this Court deems just and proper.

Respectfully submitted,

/s/ John F. Brenner
Melissa A. Chuderewicz
brennerj@pepperlaw.com
chuderem@pepperlaw.com
PEPPER HAMILTON LLP
Suite 400
301 Carnegie Center
Princeton, New Jersey 08543
(609) 452-0808
Attorneys for Plaintiff
Otsuka Pharmaceutical Co., Ltd.

Dated: July 11, 2014

Of counsel:

James B. Monroe
Paul W. Browning
Denise Main
FINNEGAN, HENDERSON,
FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, N.W.
Washington, DC 20001-4413
(202) 408-4000